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EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY*

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CERTAINLY no surgical specialty has undergone a greater technologic revolution during the last five years than urology. The evolution of treatments for symptomatic urolithiasis has been compressed from decades into years, and urologists have learned new techniques only to find them replaced by newer technological developments.

Ever since physicians of Hippocrates' time were forbidden to "cut for the stone," specialists in stone disease have cared for colics and calculi. Ancient lithotomists and modern urologists have performed surgery to remove stones from all parts of the genitourinary tract. Anatrophic nephrolithotomy, extended pyelolithotomy and coagulum pyelolithotomy are surgical techniques which have increased surgical success rates and decreased the operative loss of kidneys. Intraoperative nephroscopy with rigid and flexible scopes recently

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have given way to the percutaneous approach for extraction and ultrasonic disintegration of renal and ureteral calculi of all sizes and compositions. The rigid ureteroscope has been passed transurethrally for diagnostic as well as therapeutic stone manipulations.[1-7]

A wedding of technological advancements to clinical needs has benefited urologic patients by decreasing the need for surgery or the interruption of life styles. New solid lens and fiberoptic lighting systems, enhanced c-arm flouroscopic visualization, finely machined microsurgical instruments and widely available polyurethane sheaths and stents blended for strength and flexibility all have combined to allow urologists to become microsurgical endoscopists. The horizon for therapeutic interventional possibilities has broadened remarkably over the last five years.

And yet now a nonsurgical and noninvasive technique to disintegrate stones using shock waves has been developed and tested in West Germany. Extracorporeal shock wave lithotripsy has proved effective and safe for patient use, and it is truly the wave of the future for treatment of symptomatic stone-bearing patients.

Shock Waves

Shock waves are high energy pressure amplitudes generated in air or water by an abrupt release of energy within a small space. They propagate according to physical laws of acoustics, and are transmitted through media with low attenuation. For example, when an atomic bomb explodes in the atmosphere, a shock front representing a moving wall of highly compressed air is generated. Another familiar compression shock wave, a sonic boom, is created when an object, such as a supersonic aircraft, moves through a medium (air) faster than the speed of sound (Figure 1). Although unfocussed, the audible wave (boom) and mechanical wave (''window breaking'') are detectable evidence of this high energy form.

In contrast to the sinusoidal wave form of high frequency ultra sound, a shock wave is a summation of predominantly low frequency wave contours with a steep onset of pressure. Only when the shock wave encounters a boundary between substances of differing acoustical impedance (i.e., density) will energy be released and compressive stresses develop.

Development

During the last three decades, methods for disintegration of human calculi *in vivo* have included ultrasonic or electrohydraulic lithotripsy. These

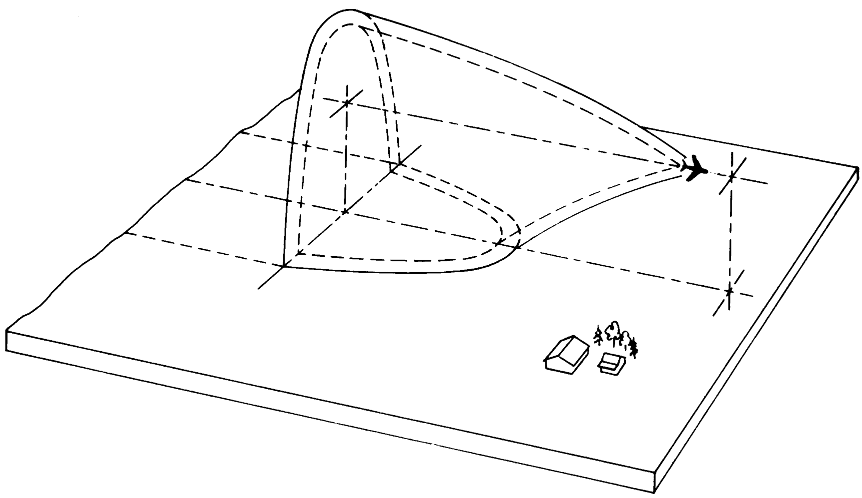

Fig. 1. Path of sonic boom

forms of energy are delivered transurethrally or percutaneously, and require direct contact between the concretion and energy source.[9] Between 1965 and 1975 worldwide investigations in the area of high-speed physics made possible the contact free destruction of concretions in the human body by the application of high energy shock waves from a distance. With the exception of chemodissolution therapy, this shock wave generated by an underwater spark gap is the only noncontact, noninvasive therapy currently available for upper urinary tract stones.[9]

In 1975 Dornier GmbH concentrated its investigational efforts to produce a shock wave whose pressure amplitude would exceed the tensile strength of a stone and yet be below the tolerance level of biologic tissue. Once generated in a controlled manner, the high energy wave had to be transmitted through the human body without attenuation and focussed to a precise treatment area. An immersion water bath was used as a coupling media for wave transmission, and an electrode positioned at the focal point of a semi-ellipsoid brass reflector generated a wave which was then reflected and focussed at the F-2 point.[9]

Initial studies revealed that the pressure amplitude at the focal point increased as voltage applied or spark gap distance increased and as discharge rate in milliseconds decreased. In other words, increased pressure amplitude resulted from widening the electrode tip separation or increasing the condenser discharge voltage. The shorter the discharge rate, the higher the shock wave intensity; the duration of the shock wave was unchanged. In addition, interposed layers of tissue did not alter the shock wave focus, and slight accompanying attenuation of the wave (damping) could be overcome by increased voltage delivered.[9] Next, the investigators demonstrated that stones of all compositions could be disintegrated *in vitro* by shock waves without significant fragment dispersion (the maximum obtainable kinetic energy of a single particle was comparable to the kinetic energy of a falling raindrop), and shock waves did not damage or injure living tissues or organs.

In 1976, using dog models with human urinary calculi inserted surgically into hydronephotic dog renal pelves, Chaussy and Schmiedt, of Ludwig Maximilian University at Klinikum Grosshadern in Munich, West Germany, demonstrated that the stones were disintegrated into spontaneously passable sized particles by shock waves passed through an immersed dog. At autopsy there was no microscopically recognizable tissues or organ degradation secondary to high energy shock wave passage.[9] After abandoning an ultrasonic localization system and developing a more precise biplanar flouroscopic one, a prototype machine for human treatment was developed in 1980. From May 1982 to October 1983 800 patients were treated at Klinikum Grosshadern.

Apparatus and Technique

The Dornier Lithotripter generates a focussed shock wave whose focal point pressures disintegrate a calculus after the patient has been properly positioned within a water bath according to biplanar flouroscopic images. Under general or regional epidural anesthesia, patients are placed on a reclining chair-like support system and submerged in a large immersion tub filled with degassified and demineralized water (Figure 2). A rapid, high voltage underwater spark discharge within an ellipsoid reflector generates a shock wave which can be focussed and transmitted through water. This high energy wave travels through body tissue (a medium similar in acoustic impedance, i.e., density, to water) with slight attenuation. At its focus point, the wave impact against the stone liberates short term high energy mechanical stresses. This stress overcomes the tensile strength of the calculus, causing disintegration. A summation of wave impacts should pulverize the calculus into sand. Voltage across the electrode determines the strength of each shock wave de-

Fig. 2. Patient in position in immersion tube ready for shock wave lithotripsy

livered, and can be varied from 18,000 to 24,000 volts.

Unlike high frequency ultrasound, these low frequency, positive pressure compressive amplitudes have good tissue penetration without significant reflection. Only at the focal point (1.5 cm^3 in volume) are maximal compression energies developed that disintegrate calculi of all compositions, while sparing any demonstrable damage to surrounding organs or tissues.

The treatment is guided and monitored by underwater biplanar flouroscopy which allows the operator to place the stone precisely at the focal point of the wave (Figure 3). The delivery of each wave is synchronized with the heart rate, as monitered by an electrocardiogram, so that mechanical stresses of unfocussed waves do not disturb the electrical conduction system of the heart. After each 100-200 waves, flouroscopy is performed to monitor stone disintegration and to check the focus (Figure 4). The entire procedure takes 45-60 minutes depending on the heart rate, and the number of shock waves delivered varies according to the stones' size, position and composition. Most patients can be discharged the day after treatment, and with adequate ambulation, hydration and oral analgesia will spontaneously pass the fragments in their voided urine over the next several days to weeks.

Clinical Trials

In 1984 six American institutions were authorized by the U.S. Food and Drug Administration to begin clinical trials utilizing the lithotripter. After review of 8,000 treatments worldwide and over 2,000 treatments in the United States, the Food and Drug Administration approved this technique in December 1984 as both effective and safe for patient use.[13,14]

Patient Selection

Symptomatic patients with active stone disease were accepted for review, and recent intravenous pyelograms were examined. Patients were categorized according to the Food and Drug Administration classification criteria (Table I). All Category A patients were medical and anesthetic good risk candidates. Absolute contraindications to extracorporeal shock wave lithotripsy treatment included cardiac pacemakers; renal artery calcification; ureteral stones below the bony pelvic brim unless they could be manipulated endoscopically to a more proximal position; distal ureteral obstruction; and serum creatinine levels greater than 3 mg/dl.

Relative contraindications assessed by individual physician operators included noncalcified or poorly visualized stones; inappropriate body habitus (short stature, obesity, skeletal immobility or fixation); ureteropelvic junction obstruction, mild to moderate; cardiac arrhythmias; staghorn calculi; medullary sponge kidneys and coagulation disorders. Relative contraindications were qualified by individual clinical assessments. Hydronephrosis, presence of ureteral stents or nephrostomies, prior renal nephrostolithotomy or surgery, previous ureteral surgery or reimplantation, horseshoe kidneys, ileal conduits and solitary kidneys were not contraindications. Paraplegic and quadraplegic patients were treated at some of the institutions.

Treatments

During the Food and Drug Administration trials, most patients underwent extracorporeal shock wave lithotripsy as inpatients, because the trials required extensive and postprocedural patient testing. Each treatment was classified either as a Category A or Category B stone (see above). A Dornier lithotripter was utilized for all treatments.

Results

The six investigational centers submitted all data to an approved data collection unit where analysis is underway. At the New York Hospital-Cornell

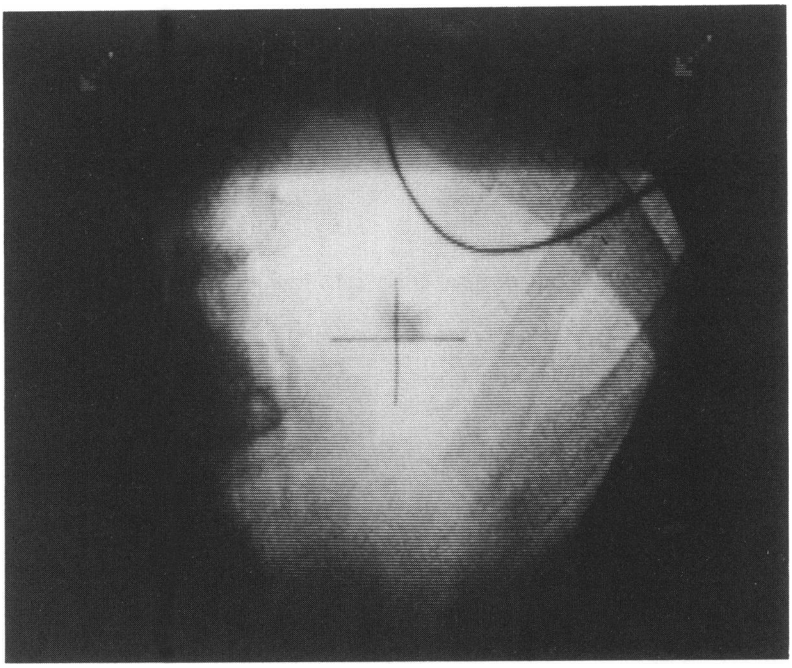

Fig. 3. Under flouroscopy stone is placed within treatment radical (see arrow)

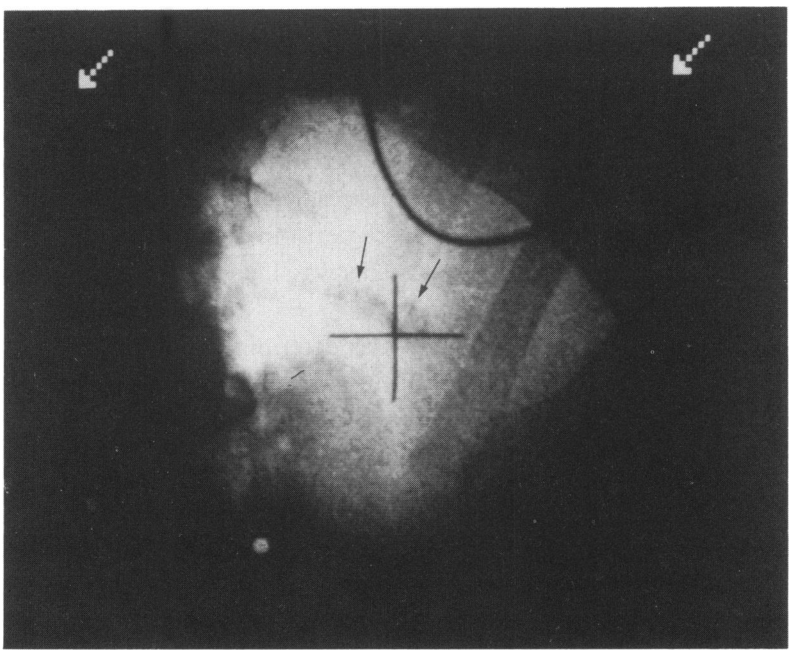

Fig. 4. Typical monitor appearance of disintegrated renal pelvic stone (see arrow)

TABLE I. PATIENT CLASSIFICATION

Category A patients
1) Solitary, densely opaque pyelocaliceal stone
2) Stone less than 2.0 cm in axial length
3) Sterile urine
4) Absence of obstruction distal to stone
5) Normal body habitus
6) Creatinine less than 3 mg/dl
7) Absence of significant aortic or renal artery calcification
Category B patients
1) Multiple pyelocaliceal stones
2) Stones larger than 2.0 cm in axial length
3) Upper ureteral stones
4) Radiolucent stones (localization facilitated by exogenous contrast material)
5) Infection stones (partial or full staghorn, positive urine cultures)

Medical Center, from May 1, 1984 to June 1, 1985, 467 patients underwent shock wave lithotripsy.[29] In total, 518 treatments were performed; of these, 5% (26 of 518) were retreatments of the same kidney, and 25 patients received bilateral treatments. Ninety-five percent of stones were completely treated during one extracorporeal shock wave lithotripsy session.

LONG-TERM RESULTS

A retrospective analysis of 277 patients (300 treatments) was performed. Information on treatment effect was available on 58% (300/518) of the procedures. Forty-two percent (127/300) of the treatments were performed on Category A stones and 58% (173/300) were performed on Category B stones. The average stone burden for all treatments was 17.8 mm. Regional anesthesia was used in 78% of the cases.

The overall stone-free rate (success) as determined by roentgenography performed at a three-month interval after treatment was 75% (224/300). Twenty-three percent (70/300) had some detectable fragments remaining, and 2% (6/300) revealed no significant disintegration or effect of extracorporeal shock wave lithotripsy. The average stone burdens (sum of stone diameters in greatest dimensions) were as follows: 15.6 mm (stone free), 25.2 mm (fragments remain) and 17.0 mm (failure). The stone-free success rate for Category A stones was 87% (111/127) and for Category B 65% (113/173). The smaller average stone burden for As (12.1 mm) contrasts

TABLE II. RESULTS

	Category A	*Category B*	*Overall (A+B)*
Success	87% (111/127)	65% (113/173)	75% (224/300)
Fragments remain	12% (15/127)	32% (55/173)	23% (70/300)
Failure	1% (1/127)	3% (5/173)	2% (6/300)
Stone burden (avg.)	12.1 mm	21.9 mm	17.8 mm

with the 21.9 mm average stone burden for Bs. 2% (6/300) of treatments failed to disintegrate the target stone (Table II). Specifically, the stone-free rate diminished in proportion to increasing stone burden (Figure 5).

For Category A stones, 91% of renal pelvic stone treatments were stone-free at three months, yet only 78% of treatments for a solitary caliceal stone were completely successful. For Category B stones, the average stone load and success rate were individualized according to stone type and location. At our unit, Category B stones were further subclassified into one of the following categories: large (greater than 2 cm), multiple, multiple large, ureteral, ureteral (manipulated to a pyelocaliceal position), ureteral with accompanying pyelocaliceal stone, stone less than 2 cm accompanied by positive urine culture, partial staghorn, complete staghorn or radiolucent and/or poorly calcified stone. Of note, approximately one third of Category B stones in this analysis were ureteral (primary or secondary ureteral fragments from previous renal extracorporeal shock wave lithotripsy.)

The lowest stone-free rates are with multiple, large calculi (43%) and full staghorn calculi (50%); these two groups also had the highest stone burdens pretreatment. For primary ureteral stones, an overall success rate of 88% was achieved. The success rate for these stones treated *in situ* (85%) was increased to 93% after successful catheter displacement. 40% of manipulation attempts were successful.[26]

The minimum hospital stay for the procedure was two days (48 hours). Patients were admitted the afternoon before treatment, and discharged by noon the day following. Patients with category A stones had a lower average stay for each treatment compared to Category B (2.6 days versus 3.5), with treatments for multiple, large stones, full staghorn stones and ureteral plus renal stones (Category B) requiring the longest hospital management before and after lithotripsy. Hospital stays averaged more than six days for treatments of stone loads greater than 40 mm. As expected, with higher total stone burdens, hospital stays increased (Figure 6).

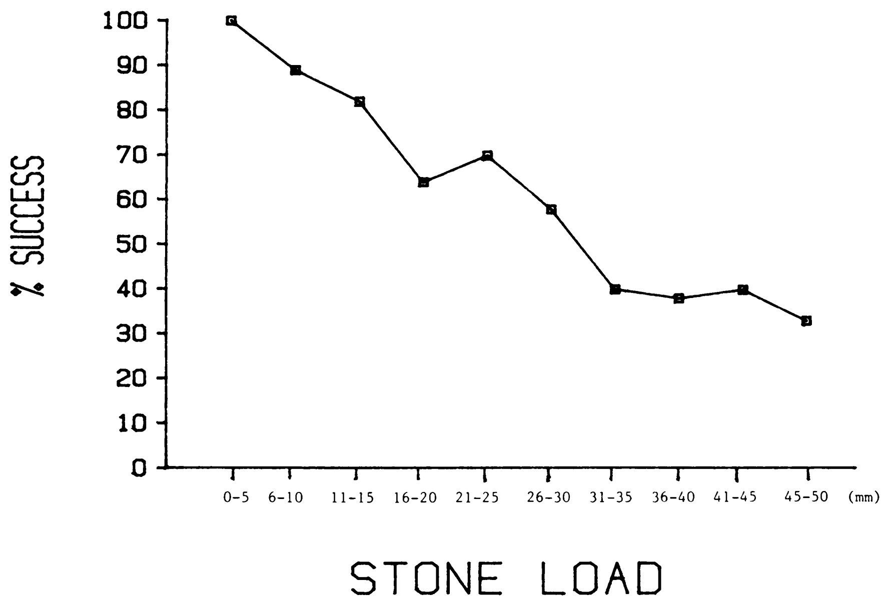

Fig. 5. Success versus stone load (mm)

ANESTHESIA

Shock wave lithotripsy requires some form of analgesia because the summation of wave impulses both at the skin level and within the focal point stimulates cutaneous and viseral sensory afferent nerves. Without analgesia, patients perceive an unpleasant "slapping" or "shock-like" pain. Either regional anesthesia (epidural or single shot spinal) or general anesthesia with intubated ventilation have been used. The length of treatment time varies from 30 to 90 minutes, with larger stones requiring longer treatments and more shock waves.

Under the continuous epidural technique, the indwelling epidural catheter isolated under a steridrape allows for supplementation of the T4 to T6 sensory level during treatment. Regional anesthesia has the advantages of an awake patient who can assist in transfer from stretcher to support system. However, tachypnea secondary to anxiety can cause rapid renal excursion during lithotripsy, and less effective disintegration as the stone moves in and out of the focal area. Consequently, intravenous sedation is often required to assure constant positioning within the target focus. General anesthesia has the advantage of controlled respiratory rates and volumes as well as

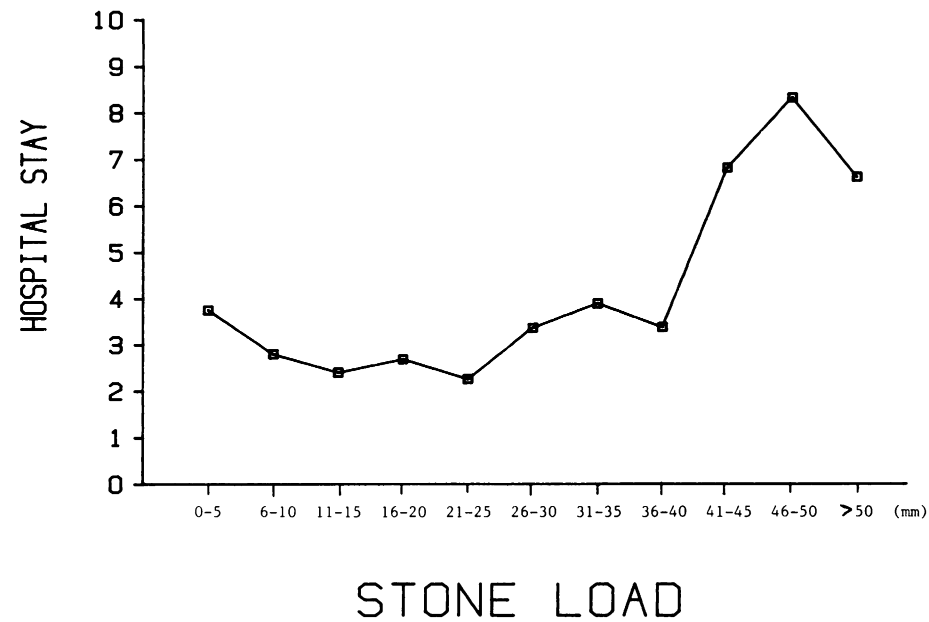

Fig. 6. Hospital stay versus stone load (mm)

assuring immobility of the patient within the immersion tube. The increased ventilatory dead space can easily be compensated for.

The patient recovery room times are not significantly different for either technique.[17] Preliminary reports of a local field technique infiltration of the flank to be treated have been received from Germany.

Complications

In general, complications during extracorporeal shock wave lithotripsy are related to anesthesia.[16,17] Hypotension, arrhythmias, chest pain, nausea, tachypnea with rapid renal excursion, abdominal and flank pain and patient's movement occur during regional (epidural or spinal) anesthesia. Immediate postprocedural complications include skin ecchymosis, flank discomfort with or without colic, fever, nausea and vomiting and urinary tract infection from bacteria liberated during stone disintegration. Rarely, obstructed pyelonephritis and/or urosepsis can occur (see secondary procedures). Symptomatic pancreatitis and chemical hepatitis have been reported.[28] Fewer than 1% of treated patients will develop symptomatic perirenal or intrarenal hematomas requiring transfusion.

Clinical Course

Symptoms during fragment passage can usually be treated by oral pain medication and hydration. Low grade fever and intermittent colic are managed on an outpatient basis. However, nausea and vomiting with abdominal ileus frequently required patient hospitalization for intravenous hydration, since adequate postlithotripsy urine flow is a fundamental key to successful fragment passage.

Most patients begin to pass some fragments within 12 hours of treatment. The higher the level of activity, i.e., in most cases the younger the patient, the more rapid and complete the stone passage. Rates of fragment passage vary, and patients with large stone burdens report intermittent fragment passage for four to eight weeks after treatment. Older patients are less likely to pass all fragments by the three-month evaluation.

Successful treatment requires both complete disintegration of the targeted calculus and complete spontaneous discharge of all fragments as monitored by a roentgenogram three months after treatment.

Complete spontaneous passage of disintegrated upper urinary tract calculi after extracorporeal shock wave lithotripsy occurs in 50%-90% of treated patients. Rate and prospects for complete stone passage depend on stone burden (size), stone location, stone composition, quality of stone disintegration, age and ambulation/hydration potential, individual anatomy (ureter calibre, prostatic hyperplasia, previous ureteral surgery or fixation, renal function and metabolic stone management (Figure 7).

Stone Composition

Original *in vitro* experimentation at Dornier demonstrated that stones of all compositions could be disintegrated with shock waves (Figure 8).[9] Clinically, the following impressions have emerged: Calcium oxalate stones disintegrate well; calcium oxalate dihydrate stones disintegrate into smaller fragments than do monohydrate stones; pure monohydrate stones can be relatively refractory to lithotripsy; pure calcium phosphate stones are often initially resistent to shock waves; uric acid calculi require more numerous and higher voltage waves for disintegration, but usually produce fine sand-size granules; infection stones (struvite-apatite) disintegrate well, unless the stone includes a large amount of matrix; and cystine stones disintegrate poorly, and fragment into pieces often larger than 5 mm which are not easily passed.

PREDICTORS FOR SUCCESS

1) Stone burden (size)
2) Stone location
3) Stone composition
4) Quality of disintegration
5) Age, ambulation/hydration potential
6) Genitourinary anatomy
7) Previous ureteral surgery/fixation
8) Renal function
9) Metabolic stone management

Fig. 7.

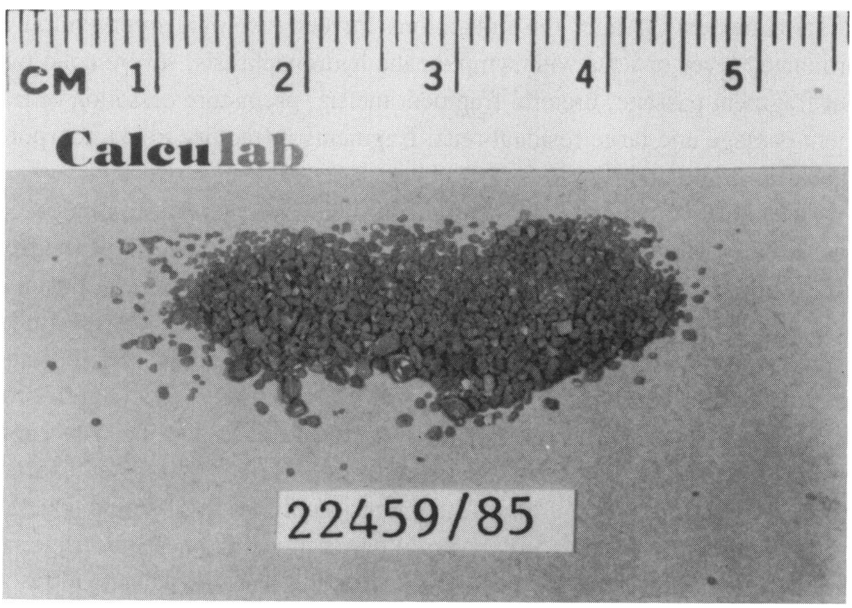

Fig. 8. Uric acid fragments

Auxillary Procedures

Preprocedural endoscopy with stent placement or stone manipulation is indicated for noncalcified stones (uric acid), poorly calcified stones, large renal pelvic stones, impacted ureteropelvic junction stones and ureteral stones. Retrograde contrast injection via ureteral catheter can enhance flouroscopic visualization. Twenty-three percent of our treatments (119/518) at New York Hospital were preceeded by auxillary procedures, in most cases performed at our institution (Figure 9).[29]

Secondary Procedures

The ureteral steinstrasse is a common radiologic picture after extracorporeal shock wave lithotripsy (Figure 10). Proximal or distal ureteral sand or fragments are seen days to weeks after treatment. Common points of temporary inertia are the proximal ureter where it crosses anteriorly over the psoas muscle, the midureter at the level of the iliac vessels and the prevesical ureterovesical junction. Patients may pass these granules daily in small amounts or sporadically after a few hours of urinary symptoms. Spontaneous passage is the usual occurrence.

Ureteral fragments can cause temporary hydronephrosis with symptomatic colic, decreased ipsilateral renal function and gastrointestinal ileus. Occasionally obstructed pyelonephritis will occur. Since most fragments progress to spontaneous passage, the indications for endourologic intervention are prolonged fever or ileus with symptomatic hydronephrosis, severe colic without fragment passage, ureteral fragment inertia, premature cessation of fragment passage and large residual renal fragments refractory to extracorporeal shock wave lithotripsy.

A secondary procedure, defined as a surgical, percutaneous or endoscopic procedure performed after lithotripsy, was necessary after 8% of the treatments in our series. Preliminary reports from Munich, Stuttgart, Japan and Los Angeles report a 5 to 11% secondary procedure rate. Our secondary endoscopy rate was 7%. Secondary endourologic procedures after lithotripsy require modification of previously described techniques.[15,18] Ureteroscopy of a distal steinstrasse is particularly difficult because a guide wire cannot be passed through the impaction; conventional baskets, loops and forceps cannot be used; multiple ureteral fragments require multiple reintroductions of the ureteroscope with accompanying ureteral edema and hemorrage; and the direct vision ureteroscope with offset lens has a small, delicate ultrasonic probe which clogs easily. The rate of secondary procedures increases in concordance with the size and complexity of the target stone for disintegration.

Fig. 9. Large, impacted ureteropelvic junction stone with associated hydronephrosis (A,B) is dislodged into renal pelvis using ureteral catheter (C) allowing effective extracorporeal shock wave lithotripsy and dispersal of fragments (D)

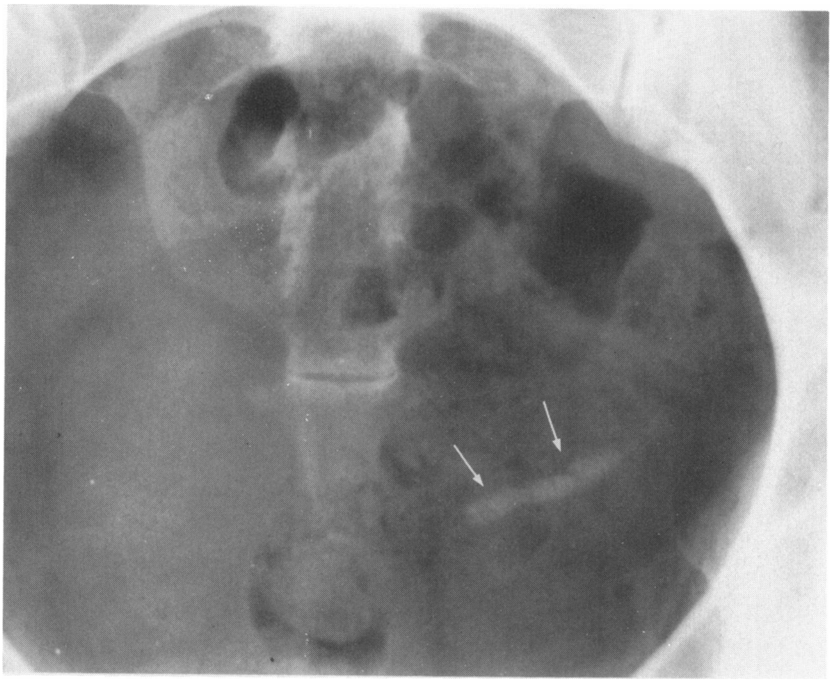

Fig. 10. Prevesical steinstrasse

URETERAL CALCULI

Extracorporeal shock wave lithotripsy of upper ureteral stones is difficult because the proximity of the ureter to the vertebral column requires rotation of the patient in the support system; given the more anterior position of the ureter as it runs along the psoas muscle, the energy of the wave is slightly diminished; flouroscopic visualization is more difficult; stones surrounded by an edematous indurated ureter do not disintegrate as freely as renal pelvic stones; circumferential disintegrated fragments cannot separate from the stone, and so a new interface for the next shockwave is not created. Therefore, it is advantageous to displace the stone to the kidney or at least proximal to its place of lodgement for effective disintegration (Figure 11). In a series of 66 primary ureteral stones, 27 were effectively dislodged for a shockwave disintegration success rate of 93%. However, for the 39 ureteral stones treated *in situ*, 85% of the treatments were still successful. Of note, the average stone size was 9.7 mm (Table III).[26]

Consequently it will become increasingly acceptable to treat upper ure-

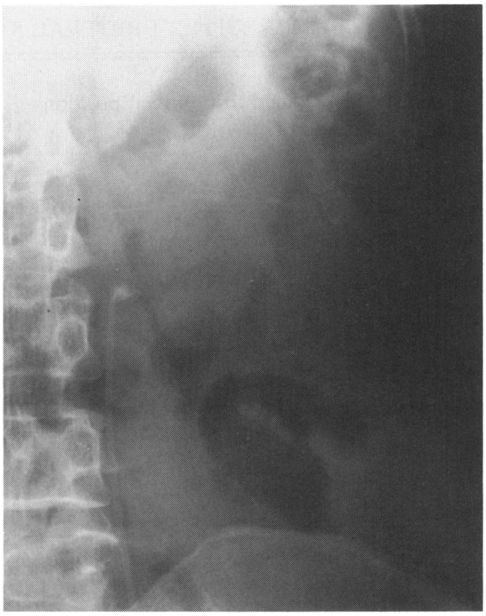

Fig. 11. Mid-ureteral stone being manipulated retrograde

teral stones of significant size when they first present symptomatically. Although 80% of symptomatic ureteral stones will pass spontaneously, stones larger than 8 mm in diameter have a less than 50% chance of passing without intervention.[19,20] When such stones are visualized in the upper ureter, a urologist may choose immediately to manipulate the stone endoscopically and reposition it within the kidney. An internal ureteral catheter (double J) can be left indwelling before elective extracorporeal shock wave lithotripsy. Alternatively, if the urologist elects a conservative course of observation, lithotripsy of the impacted stone which fails to progress over six to eight weeks may be less successful. The more distal the stone in the ureter, the more difficult it is to position the patient in the support system for extracorporeal shock wave lithotripsy. Ureteral stones below the pelvic brim usually cannot be treated using this form of lithotripsy unless they be manipulated retrograde. Preliminary reports utilizing extracorporeal shock wave lithotripsy for distal ureteral stones demonstrate better disintegration of calculi which do not overlie the bony sacroiliac joints. Obviously, prevesical stones surrounded by pelvic soft tissue are more accessible to shockwave penetration.

TABLE III. CONCLUSIONS: UPPER URETERAL STONES

88% stone free after treatment
93% stone-free success if stone manipulated to proximal position
5% failure rate
All patients underwent pretreatment cystoscopy
No adverse effect of indwelling stent

Complex or Staghorn Calculi

Although 98% of stones are successfully disintegrated, larger volumes of particles are associated with lower stone free rates and high secondary procedure rates (Figure 12). Disintegration of branched, dendritic calculi produces a large stone burden for spontaneous passage. Often, numerous sequential treatments are needed, and if the staghorn calculus has caused significant intrarenal dilation and distortion of the collecting system, prolonged renal retention of fragments is common. Posttreatment hydronephrosis combined with bacilluria released from infection stones make these complex cases difficult to manage with extracorporeal shock wave lithotripsy monotherapy.

Our plan for complex stones (large renal pelvic, multiple and large renal, partial and complete staghorns and cystine) is a combination approach utilizing percutaneous surgery and extracorporeal shock wave lithotripsy. Percutaneous removal of the pelvic and lower caliceal component prior to lithotripsy will allow subsequent fragment passage through the nephrostomy tube as well as drain the involved kidney. Decreased disintegrated intrarenal stone burden increases successful spontaneous passage of fragments and subsequent stone-free intervals. The retreatment and secondary procedure rates are less, and the hospital stay is decreased.

Therefore, our approach has been one of the following: percutaneous nephrostolithotomy and then extracorporeal shock wave lithotripsy of remaining stone burdens, with indwelling nephrostomy tube; lithotripsy followed immediately by percutaneous nephrostomy and later nephrostolithotomy if required by residual stone burden; multiple, sequential treatments to only part of the staghorn each time (staged). Only young, ambulatory, motivated patients are selected for the sequential approach, and all patients with infection stone history are given 24 hours of hydration and parenteral antibiotics prior to and after the procedure. These patients are also given oral antibiotics until they are stone free.

Cystine Stones

Cystine stones are relatively resistant to shock waves, and large stones tend

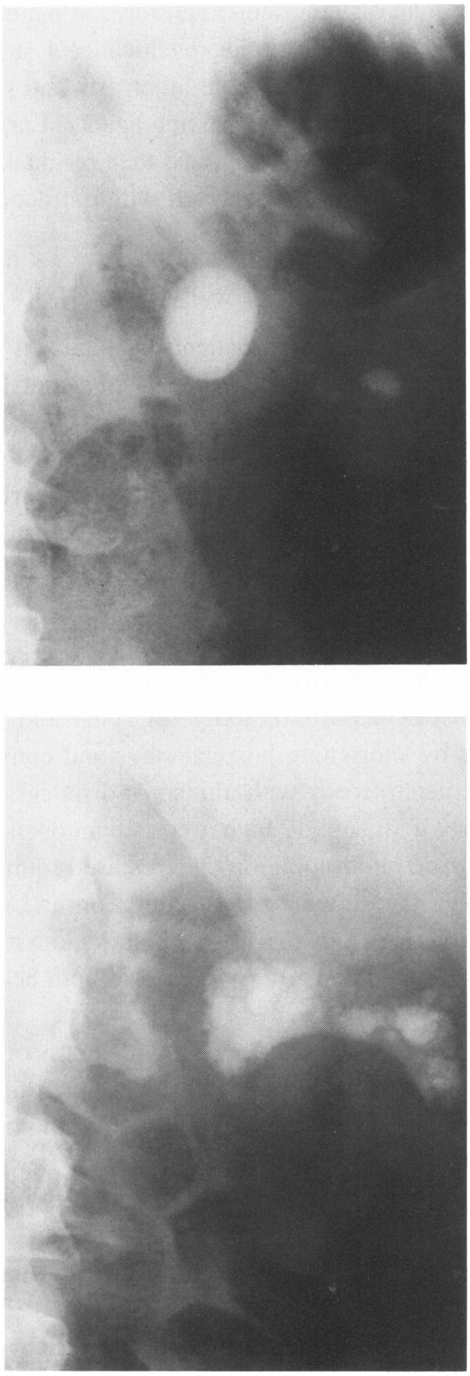

Fig. 12. Large renal stone (A) after disintegration with 2,400 shockwaves (B)

to fragment rather than disintegrate. Therefore, in patients who have failed metabolic management, small mobile pyelocaliceal stones can be treated primarily by extracorporeal shock wave lithotripsy and subsequently by oral therapy or renal irrigation with alkalinizing agents. Large stones should be removed with percutaneous lithotripsy, and then residual fragments irrigated via the nephrostomy tube or disintegrated with extracorporeal shock wave lithotripsy.

BACKGROUND AND PERSPECTIVE

The average annual incidence of patients hospitalized in the United States for urolithiasis is 1.42 per 1,000 population, with a slightly higher rate (1.84) in the South and slightly lower rates in the East (1.16) and the West (1.00). In the United States since 1980, 300,000 to 400,000 patients each year were hospitalized with the diagnosis of stones in the kidney or ureter, and approximately 40% (or more than 120,000) of these per year underwent a surgical or endoscopic procedure for stone removal at a cost greater than 1.4 billion dollars.[21,22]

Over the last five years major technologic advances in endourologic instrumentation have allowed extraction of symptomatic urinary calculi without surgery. Percutaneous nephrolithotomy for renal and ureteral stones has benefited patients by shortening hospital stays and convalescence periods. Though effective, nephroscopy with ultrasonic disintegration of calculi is an invasive procedure, with slightly higher costs than open surgery when multiple flouroscopic and endoscopic procedures are required for complex renal calculi.[23] Given the above cost consideration and the increasing incidence of symptomatic stone disease, emphasis on a less invasive and complicated surgical treatment are of interest to both health care consumers and providers.[21,22]

Since 1982 the experience of Chaussy with extracorporeal shock wave lithotripsy in Munich, West Germany, has predicted that 80% of symptomatic upper urinary tract stones could be treated with noncontact disintegration by shockwaves. In a series of 1,000 carefully selected cases reported by Chaussy, a stone-free rate of 90% was achieved with minimal complications.[25]

Other European centers have confirmed the efficacy of shockwave lithotripsy, but specific stone-free rates between 60 and 90% have been reported depending on stone size, location, composition and prior percutaneous extraction procedures.[24,27] Our overall stone-free rate of 75% was

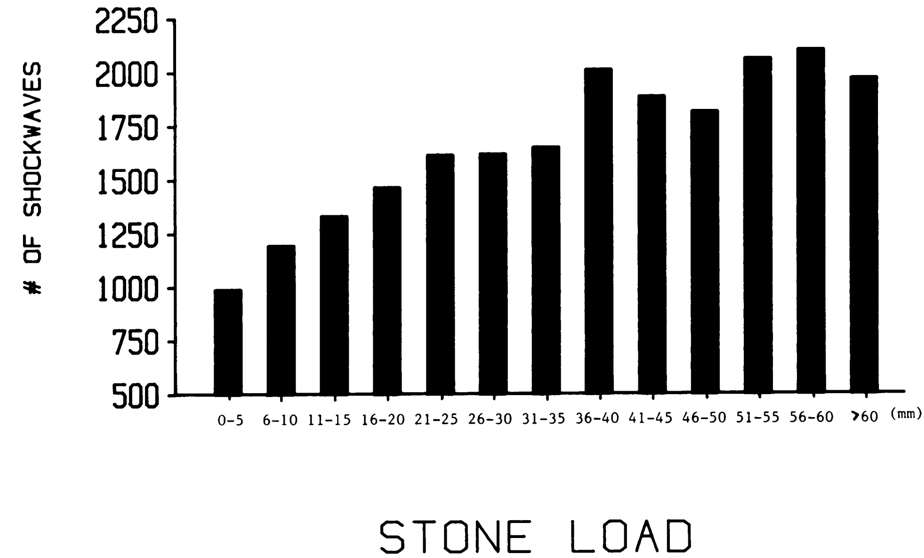

Fig. 13. Shock waves delivered versus stoneload (mm)

achieved in 300 treatments at our center; the average stone burden was 17.8 mm. While lower than initially expected, the rate parallels the Food and Drug Administration monitored American clinical trial results.[28]

In general, an 85 to 90% success rate with Category A stones can be expected. This contrasts with a 65 to 70% stone-free rate for Category B stones. The decrease in successful spontaneous passage is expected as total stone burden in the kidney increases. Two to three percent of treatments are failures, confirming a 98% disintegrative effect of extracorporeal shock wave lithotripsy on all treated stones. The number of shock waves administered increases in proportion to the total stone burden, as does the flouroscopy time and treatment time (Figure 13).

Although our experience supports the association of longer hospital stay with larger stone burdens, it is impossible to predict which patients with small stones will require additional hospital days for hydration and analgesia. Both patient and family concerns about this new treatment often lengthened individual hospital stay, and the large number of patients referred to a unit from outside its geographic area often made early discharge impossible. Outpatient treatment of selected individuals with Category A or ureteral stones is certainly possible, and will become more frequent as lithotripter units are available locally to each community.

TABLE IV. CONCLUSIONS

Stone burdens > 40 mm
Require more shock waves
Require longer hospital stay
Require more secondary procedures
Require more retreatments
Lower success rate
Cystine stones disintegrate poorly
Infection stones disintegrate well

THE FUTURE

Certainly, questions yet to be answered concerning extracorporeal shock wave lithotripsy include the following: The fate of residual fragments, the effect on stone incidence, role of periprocedural antibiotics, preprocedural stone softeners, effect of temporary ureteral stents on subsequent fragment passage, selection of patients for outpatient treatment, postprocedural chemolysis, long-term renal effect of shock waves, timing of lithotripsy in relation to clinical course and new generation lithotripters.

Second and third generation lithotripters are currently being designed and produced. New concepts attempt to create a new wave generator improving or eliminating the electrode and thus the expense of electrode replacement, a new focus device that can vary the currently fixed F-2 focal length, improved flouroscopic or ultrasonic visualization systems, use of cushion fluid couplers rather than an immersion bath, and miniaturization of system for possible eventual office use.

SUMMARY

Experience with shock wave lithotripsy confirms that at least 80% of symptomatic upper urinary tract stones (above the bony pelvis) can be treated by extracorporeal shock wave lithotripsy. Under local, regional or general anesthesia, a 45-minute shock wave lithotripsy treatment will produce a detectible disintegrative effect after 98% of treatments and will allow 75% of patients to be stone free three months after procedure. However, stone-free success rates must be individualized depending on stone size, position, composition and patient selection. Combined treatment utilizing percutaneous surgery or multiple extracorporeal shock wave treatments will be necessary for complex stones with large stone burdens (Table IV), and 7% of selected patient stones will require a secondary endoscopic procedure to facilitate complete stone passage. Currently, ureteroscopy remains the treatment of choice for distal ureteral calculi.

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